510(k) Summary
21 CFR 807.92

JAN 10 2013

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the information upon which substantial equivalence determination is based is as follows:

1. Submitter Information:

Applicant:	Bard Peripheral Vascular, Inc. 1625 West 3rd Street Tempe, Arizona 85281
Phone:	480-638-2954
Fax:	480-449-2546
Contact:	Sarah McCartney, Regulatory Affairs Associate
Date:	December 18, 2012

2. Subject Device:

Device Trade Name:	**SenoMark® Ultra Breast Tissue Marker**
Common or Usual Name:	Tissue Marker
Classification:	Class II
Classification Name:	Marker, Radiographic, Implantable (Product Code NEU)
Review Panel:	General & Plastic Surgery
Regulation Number:	21 CFR 878.4300 (Implantable Clip)

3. Predicate Device:

SenoMark® Breast Tissue Marker (K050090; cleared February 7, 2005)

4. Summary of Change:

A line extension to provide permanent ultrasound visibility and two unique shapes for use with each VAB probe.

5. Device Description:

The SenoMark® Ultra Breast Tissue Marker is a sterile, single use device, comprised of a disposable applicator and an implantable marker. The marker contains three PGA pads which are visible via ultrasound imaging for approximately 3 weeks and are

essentially resorbed by the body after approximately 12 weeks. The center PGA pad contains a metallic wireform interwoven with a PVA polymer. The non-resorbable PVA polymer enhances viewing under ultrasound. The wireform is made of Titanium or BioDur™ 108 in a ribbon or coil shape respectively. The wireform is visible radiographically on a permanent basis. The SenoMark® Ultra Breast Tissue Marker is intended for breast tissue marking during a breast biopsy procedure.

6. Indications for Use of Device:

The SenoMark® Ultra Breast Tissue Marker is intended to radiographically and sonographically mark breast tissue during a percutaneous breast biopsy procedure.

7. Technological Comparison to Predicate Devices:

The technological characteristics of the subject device are substantially equivalent to those of the predicate device, in terms of following:

- Intended use
- Indications for use
- Target population
- Fundamental scientific technology
- Operating principle
- Resorbable implant design and materials
- Packaging materials and configuration
- Sterility

The subject device is a modification of the predicate device to replace the wireform in the center PGA pad with the wireform with PVA used in the referenced BPV devices (K042341 and K090547). The subject device and the predicate device are different in the following manner:

- Permanent implant design and materials
    - The subject device replaces the Titanium "O" or Stainless Steel "M" wireform located in the center of the resorbable PGA pad with a titanium ribbon with a PVA insert or BioDur™ 108 coil wireform with a PVA insert (see Figure 1). These permanent implants are currently used on legally marketed BPV breast tissue markers (reference K042341 and K090547).

Ribbon with PVA

Coil with PVA

Figure 1: New Wireform Shapes of the Subject Device

- Performance specifications
  - With the change to the legally marketed UltraClip II US wireforms, the performance specifications for ultrasound imaging and MRI compatibility will now include permanent ultrasound visibility and scanning in up to a 3-Tesla MR system. These specifications are identical to the specifications provided in the reference devices.

8. Performance Testing Summary:

To demonstrate substantial equivalence of the subject device to the predicate device, the technological characteristics and performance criteria were evaluated. Using the FDA guidance document, "Design Control Guidance for Medical Device Manufacturers," dated March 11, 1997, and internal risk assessment procedures, the following non-clinical tests were performed:

- Visual Inspection of Product for Pre-Deployment
- Inversion Test
- Deployment Force
- Read and Understand the IFU

The results demonstrate that the technological characteristics and performance criteria of the SenoMark® Ultra Breast Tissue Marker is comparable to the predicate device and that it performs as safely and as effectively as the legally marketed predicate device.

9. Conclusion:

The SenoMark® Ultra Breast Tissue Marker is substantially equivalent to the legally marketed predicate device, the SenoMark® Breast Tissue Marker (K050090).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

C.R. Bard, Incorporated
% Ms. Sarah McCartney
Regulatory Affairs Associate
1625 West 3rd Street
Tempe, Arizona 85281-1740

January 10, 2013

Re: K123911
Trade/Device Name: SenoMark® Ultra Breast Tissue Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: NEU
Dated: December 18, 2012
Received: December 19, 2012

Dear Ms. McCartney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123911

Device Name: SenoMark® Ultra Breast Tissue Marker

Indications for Use: The SenoMark® Ultra Breast Tissue Marker is intended to radiographically and sonographically mark breast tissue during a percutaneous breast biopsy procedure.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K123911